Medicare Program Integrity Manual
Chapter 13 – Local Coverage Determinations

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(Rev. 510, 04-11-14)

Transmittals for Chapter 13

reasonable and necessary. If a contractor chooses to apply these kinds of policy provisions (whether in NCD or other national coverage provisions in interpretive manuals, or LCDs) during prepay review, they should not do so via automated review if documentation is to be submitted with the claim for manual review of such claims.

When strong clinical justification exists, contractors may also develop LCDs that contain absolute words such as "is never covered" or "is only covered for". When phrases with absolute words are clearly stated in LCDs, contractors are not required to make any exceptions or give individual consideration based on evidence. Contractors should create edits/parameters that are as specific and narrow as possible to separate cases that can be automatically denied from those requiring individual review.

13.5.4 - LCD Requirements That Alternative Item or Service Be Tried First
(Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractors should incorporate into LCDs the concept that use of an alternative item or service precedes the use of another item or service. This approach is termed a "prerequisite." Contractors shall base any requirement on evidence that a particular alternative is safe, as effective, or appropriate for a given condition without exceeding the patients' medical needs. Prerequisites shall be based on medical appropriateness, not on cost effectiveness. Non-covered items (e.g., pillows to elevate feet) may be listed. Any prerequisite for drug therapy shall be consistent with the national coverage decision for labeled uses. Whenever national policy bases coverage on an assessment of need by the beneficiary's provider, prerequisites should not be included in LCDs. As an alternative, contractors may use phrases in proposed LCDs like "the provider should consider..."

13.6 - LCD Format
(Rev. 71, 04-09-04)

All contractor LCDs shall be listed in the Medicare Coverage Database.

All LCDs shall be posted on the contractor's Web site in HyperText Markup Language (HTML). The Medicare Coverage Database has a feature that will allow a contractor to "save as HTML" a file of a recently entered LCD. Contractors should alter the appearance of the HTML file to meet their own Web site needs, e.g., change the background color.

13.6.1 - AMA Current Procedural Terminology (CPT) Copyright Agreement
(Rev. 71, 04-09-04)

Any time a CPT code is used in publications on the contractor Web site or in other electronic media such as tapes, disks or CD-ROM, contractors shall display the AMA copyright notice in the body of each LCD. Contractors shall use a point and click license on a computer screen or Web page any time CPT codes are used on the Internet.

13.7 - LCD Development Process
(Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

When a new or revised LCD is needed, contractors do the following:

- Contact the CMD facilitation contractor, other contractors, the local carrier or intermediary, the DMERC (if applicable), the Medicare Coverage Database or QIOs (formerly PROs) to inquire if a policy which addresses the issue in question already exists;

- Adopt or adapt an existing LCD, if possible; or

- Develop a policy if no policy exists or an existing policy cannot be adapted to the specific situation.

The process for developing the LCD includes developing a draft LCD based on review of medical literature and the Contractor's understanding of local practice.

A. Multi-State Contractors

A contractor with LCD jurisdiction for two or more States is strongly encouraged to develop uniform LCDs across all its jurisdictions. However, carriers shall continue to maintain and utilize CACs in accordance with this chapter.

13.7.1 - Evidence Supporting LCDs

(Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and

- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

    - Scientific data or research studies published in peer-reviewed medical journals;

    - Consensus of expert medical opinion (i.e., recognized authorities in the field); or

    - Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.

Less stringent evidence is needed when allowing for individual consideration.

13.7.2 – LCDs That Require A Comment and Notice Period
(Rev. 71, 04-09-04)

Contractors shall provide for both a comment period and a notice period in the following situations:

- All New LCDs
- Revised LCDs that Restrict Existing LCDs - Examples: adding non-covered indications to an existing LCD; deleting previously covered ICD-9 codes.
- Revised LCDs that make a Substantive Correction - If the contractor identifies an error published in an LCD that substantively changes the reasonable and necessary intent of the LCD, then the contractor shall extend the comment and/or notice period by an additional 45 calendar days.

13.7.3 - LCDs That Do Not Require a Comment and Notice Period
(Rev. 71, 04-09-04)

When a comment and notice period is unnecessary, contractors may immediately publish a revised LCD electronically (e.g., Medicare coverage database, contractor Web site, email). In the following situations, the comment and notice processes are unnecessary:

- Revised LCD that Liberalizes an Existing LCD - For example, a revised LCD expands the list of covered indications/diagnoses. The revision effective date may be retroactive.
- Revised LCD Being Issued for Compelling Reasons - SHALL OBTAIN RO (for PSCs, the GTL, Co-GTL, and SME) APPROVAL - For example, a highly unsafe procedure/device.
- Revised LCD that Makes a Non-Substantive Correction - For example, typographical or grammatical errors that do not substantially change the LCD. The revision effective date may be retroactive.
- Revised LCD that makes a Clarification - For example, adding information that clarifies the LCD but does not restrict the LCD. The revision effective date may be retroactive.
- Revised LCD that Makes a Non-discretionary Coverage/Payment/Coding Updates - Contractors shall update LCDs to reflect changes in NCDs, coverage provisions in interpretive manuals, payment systems, HCPCS, ICD-9 or other standard coding systems within the timeframes listed in §13.4C. The revision effective date may be retroactive depending on the effective date of the NCD, etc.

- Revised LCD to Make Discretionary Coding Updates That Do Not Restrict -adding revisions that explain a coding issue so long as the revision does not restrict the LCD. The revision effective date may be retroactive.

- **Revised LCD to Effectuate an Administrative Law Judge's Decision on a BIPA 522 challenge.**

13.7.4 - LCD Comment and Notice Process
(Rev. 71, 04-09-04)

When a new or revised LCD requires comment and notice (See §13.7.2) contractors shall provide a minimum comment period of 45 calendar days on the draft LCD. After the contractor considers all comments and revises the LCD as needed, the contractor shall provide a minimum notice period of 45 calendar days on the final LCD.

Contractors shall solicit comments from the medical community. Carriers solicit comments from the Carrier Advisory Committee (CAC.) DMERCs solicit comments through the DMERC Advisory Process (DAP.) Contractors respond to comments either individually or via a comment/response document (see §13.7.4.2). Where appropriate, the contractor shall incorporate the comments into the final LCD. Contractors notify providers of the LCD effective date. New LCDs may not be implemented retroactively.

13.7.4.1 - The Comment Period
(Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

A. When the Comment Period Begins

For LCDs that affect items or services submitted to carriers, the comment period begins at the time the policy is distributed to the CAC either at the regularly scheduled meeting or in writing to all members of the CAC. Contractors shall distribute these draft LCDs to the CAC members via hardcopy or via email.

For LCDs that affect items or services submitted to intermediaries, the comment period begins when the policy is distributed to medical providers or organizations. Contractors may distribute these draft LCDs to medical providers and organizations via:

Hardcopy mailing of the entire draft LCD,

- Hardcopy mailing of the title and Web address of the draft LCD, or

- E-mail containing the title and Web address of the draft LCD.

B. When the Comment Period Ends

Contractors shall provide a minimum comment period of 45 calendar days. Contractors have the discretion but are not required to accept comments submitted after the end of the comment period.

C. Draft LCD Distribution

When a new or revised LCD requires comment and notice (outlined in this chapter), all contractors shall solicit comments and recommendations on the draft LCD and get input from, at least:

- Groups of health professionals and provider organizations that may be affected by the LCD;
- Representatives of relevant specialty societies;
- Other intermediaries/carriers;
- Quality Improvement Organizations (formerly known as PROs) within the region;
- Other CMDs within the region;
- General public (as outlined in this chapter);
- The regional office, associate regional administrator, for distribution to the appropriate regional staff (e.g., coverage experts, reimbursement experts). The RO (for PSCs, the GTL, Co-GTL, and SME) staff will review the LCDs for any operational concerns; and
- The appropriate Advisory process:
    - The CAC, for carriers (See §13.8.1)
    - The DAP, for DMERCs (See §13.8.2)

Contractors shall indicate in each distribution the date the comment period ends.

D. Draft LCD Open Meetings

Contractors shall provide open meetings for the purpose of discussing draft LCDs. Carriers shall hold these open meetings prior to presenting the policy to the CAC. To accommodate those who cannot be physically present at the meetings, contractors shall provide other means for attendance (e.g., telephone conference) and accept written or e-mail comments. Written and e-mail comments shall be given full and equal consideration as if presented in the meeting. Members of the CAC may also attend these open meetings.

Interested parties (generally those that would be affected by the LCD, including providers, physicians, vendors, manufacturers, beneficiaries, and caregivers) can make presentations of information related to draft policies. Contractors shall remain sensitive to organizations or groups which may have an interest in an issue (e.g., laboratories, providers who provide services in nursing facilities, home care, or hospice and the associations which represent the facilities/agencies) and invite them to participate in meetings at which a related LCD is to be specifically discussed.

13.7.4.2 - Draft LCD Web site Requirements
(Rev. 71, 04-09-04)

Draft LCD on the Contractor Web site

Contractors shall post draft LCDs on their Web sites. The Web site shall clearly indicate the start and stop date of the comment period and list an e-mail and postal address to which comments can be submitted.

LCD Status Page

Contractors shall post to their Web sites an LCD status page that includes the draft LCD title, date of release of draft LCD for comment, e-mail and postal address for comments to be sent, end date for comment period, current status (see the following status indicators), Date of Release for Notice, and Web site link to the active LCD (i.e., the notice period is complete and the policy is in effect.)

LCD Status Indicators
D = draft under development; not yet released for comments
C = draft LCD released for comment
E = formal comment period has ended; comments now being considered
F = final new/revised LCD has been issued for notice.
A= active policy; notice period complete and the policy is in effect

Comment/Response Document

Contractors shall post to their Web sites a summary of comments received concerning the draft LMRP/LCD with the contractor's response. This comment/response document shall be posted prior to or on the start date of the notice period. The comment/response document shall be posted (remain visible) on the Web for at least a 6 month period.

The MCD allows users to attach comment/response documents to their draft document which will be visible when the LCD is reviewed.

13.7.4.3 - The Notice Period
(Rev. 71, 04-09-04)

When a new or revised LCD is issued following a comment period (see §13.7.2), contractors shall ensure that the effective date follows a minimum notice period of 45 calendar days.

A. When The Notice Period Begins

Contractors shall make final LCDs public via publication on their Web site. A summary of the LCD shall be published in a news bulletin.

B. When The Notice Period Ends

The notice period ends 45 calendar days after the notice period begins unless extended by the contractor. If the notice period is not extended by the contractor, the effective date of the LCD is the 46th calendar date after the notice period began.

13.7.4.4 - Final LCD Web Site Requirements
(Rev. 71, 04-09-04)

A. Final LCD on the Contractor Web Site

Contractors shall post all final LCDs on their Web Site. Every contractor Web site shall contain all final LCDs for that contractor. The number of active LCDs in the Medicare Coverage Database should equal the number of final LCDs on the contractor Web Site.

Contractors who are an intermediary and a carrier within the same corporation shall have separate Web pages for their LCDs. Contractors shall notify all providers of the contractor LCD Web address. If a contractor becomes aware of a provider without web access, the contractor shall advise providers that they may request hard copy LCDs.

B. Final LCD in the Medicare Coverage Database (MCD)

The public can access the MCD at www.cms.hhs.gov/**mcd.**

Contractors shall update the MCD when they issue a new or revised LCD or retire an existing LCD.

Contractors shall develop a mechanism for ensuring the accuracy of the information entered into the MCD. This mechanism shall include, at a minimum, a process by which data that is entered into the database is reviewed and verified for accuracy within four days of appearing to the public on the Web.

13.8 - The LCD Advisory Process
(Rev. 71, 04-09-04)

13.8.1 - The Carrier Advisory Committee
(Rev. 99, Issued: 01-21-05, Effective: 03-24-04, Implementation: 02-22-05)

Carriers shall establish one CAC per State. Where there is more than one carrier in a State, the carriers shall jointly establish a CAC. If there is one carrier for many States, each State shall have a full committee and the opportunity to discuss draft LCDs and issues presented in their State. Carriers maintain a current directory of CAC members which is available to CO, RO (for PSCs, the GTL, Co-GTL, and SME) staff, and the provider community on request. Carriers that develop identical policies for their entire jurisdiction may establish a single CAC if they are granted a waiver from the CO (for PSCs, the GTL, Co-GTL, and SME). In order to obtain a waiver from the CO (for PSCs, the GTL, Co-GTL, and SME), contractors shall obtain agreement from CAC members within the jurisdiction.

13.8.1.1 - Purpose of the CAC
(Rev. 71, 04-09-04)

The purpose of the CAC is to provide:

- A formal mechanism for physicians in the State to be informed of and participate in the development of an LCD in an advisory capacity;
- A mechanism to discuss and improve administrative policies that are within carrier discretion; and
- A forum for information exchange between carriers and physicians.

Carriers shall clearly communicate to CAC members that the focus of the CAC is LCDs and administrative policies and not issues and policies related to private insurance business. The CAC is not a forum for peer review, discussion of individual cases or individual providers. While the CAC shall review all draft LCDs, the final implementation decision about LCDs rests with the CMD.

The CMD jointly develops the agenda with the co-chair representing the CAC to include concerns about LCDs and local administrative issues.

13.8.1.2 - Membership on the CAC
(Rev. 71, 04-09-04)

The CAC is to be composed of physicians, a beneficiary representative, and representatives of other medical organizations. Each is individually described in Exhibit 3.

13.8.1.3 - Role of CAC Members
(Rev. 71, 04-09-04)

CAC members serve to improve the relations and communication between Medicare and the physician community. Specifically, they:

- Disseminate proposed LCDs to colleagues in their respective State and specialty societies to solicit comments;
- Disseminate information about the Medicare program obtained at CAC meetings to their respective State and specialty societies; and
- Discuss inconsistent or conflicting MR policies.

13.8.1.4 - CAC Structure and Process
(Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

A. Number of Representatives

Each specialty shall have only one member and a designated alternate with approval of committee co-chairs. Additional members may attend when policies that require their expertise are under discussion. Carriers maintain a current local directory of CAC members

that is available to CO, RO (for PSCs, the GTL, Co-GTL, and SME), or the provider community on request.

B. Tenure

Carriers have discretion to establish the duration of membership on the committee. The term should balance the duration of time needed to learn about the process to enhance the level of participation and functioning with the desire to allow a variety of physicians to participate. Consider a 2-3 year term.

C. Co-Chairs

The CAC shall be co-chaired by the contractor medical director and one physician selected by the committee. The co-chairs:

- Run the meetings and determine the agendas;
- Provide the full agenda and background material to each committee member at least 14 days in advance; and
- Encourage committee members to discuss the material and disseminate it to interested colleagues within their specialty and to clinic or hospital colleagues for whom the item may be pertinent. The members may bring comments back to the meeting or request that their colleagues send written comments to the CMD separately.

Attendance at the meeting is at the discretion of the committee members. If the item is of importance to their specialty, encourage members to attend or send an alternate. This is the primary forum for discussion of proposed LCDs developed by the CMD. The 45-calendar-day comment process required for all LCDs starts when the draft LCD is distributed to the committee members. (See PIM Chapter 13 §13.7.4.1).

Co-chairs present all proposed LCDs to the CAC for discussion. If the need arises to develop and implement LCDs before the next scheduled meeting, they solicit comments from committee members by mail or e-mail.

D. Staff Participation

The Director of Medicare Operations shall assure that appropriate contractor staff attends to address administrative issues on the agenda. Other staff may also be required to attend include:

- Professional relations representative;
- MR manager and
- MFIS/PSC Network.

E. Location

Carriers work with the State medical society and committee members to select a meeting location that will optimize participation of physician committee members.

F. Frequency of Meetings

Hold a minimum of 3 meetings a year, with no more than 4 months between meetings. In the circumstance where a contractor is switching from 4 CAC meetings per year to 3 meetings, it is acceptable to have more than 4 months between the meetings. However, the contractor shall notify the RO (for PSCs, the GTL, Co-GTL, and SME) that this one time occurrence is taking place.

G. Data

Each meeting should include a discussion and presentation of comparative utilization data that has undergone preliminary analysis by the carrier and relates to discussion of proposed LCD. Carriers solicit input from CAC members to help explain or interpret the data and give advice on how overutilization should be addressed. The use of data to illustrate the extent of problem billing (e.g., average number of items or services per 100 patients) might help justify the need for a particular policy. The comparative data should be presented using graphs, charts, and other visual methods of presenting data. Carriers may present egregious individual provider's data as long as the provider's identification is not disclosed or cannot be deduced.

H. Payment for Participation

Participation in the CAC is considered a service to physician colleagues. Carriers do not provide an honorarium or other forms of compensation to members. Expenses are the responsibility of the individuals or the associations they represent.

I. Recordkeeping

Carriers keep minutes of the meeting and distribute them to members. Carriers submit the following items from CAC meetings to the RO MR staff (for PSCs, the GTL, Co-GTL, and SME) within 10 days following the meetings:

- A copy of the meeting agenda (include the date of the meeting);
- A prompt copy of meeting minutes (not approved);
- A copy of the approved minutes from the prior meeting, including a summary of this discussion and the number of attendees, broken down into committee members, alternates or observers and RO staff (for PSCs, the GTL, Co-GTL, and SME); and
- Tentative date of the next meeting.

Contractors should (but are not required to) prepare a version of the CAC minutes to be placed on their Web site. This version could differ from a more detailed internal version. Contractors shall assure that the Web site version of the minutes does not include any information that would be protected by FOIA's exemption (b)(6) -- information that would be an invasion of personal privacy (such as a CAC member's home phone number) or any other kind of sensitive information. When contractors receive a request for a hard copy of CAC minutes, the request

should go to the contractor's FOIA coordinator for processing through the freedom of information request process.

J. Communicating With CO on National Issues

While the CMD should encourage CAC members to work through their respective organizations and Practicing Physicians Advisory Council (PPAC) to effect national policy, the CAC is not precluded from commenting on these issues. When appropriate, the CMD may choose to forward a formal letter to CMS CO from the CAC. Send these letters through the RO, where they will be answered or forwarded to the appropriate component in CO for response.

K. Support for Beneficiary Member

Provide individual support to the beneficiary representative in understanding the CAC role and process. This includes assisting the beneficiary representative in understanding the LCDs so they are better able to determine the effect of the policy on the beneficiary community. Carriers are encouraged to find ways to involve the beneficiary community in efforts to stem abuse through LCD development.

13.8.2 - Durable Medical Equipment Regional Carrier (DMERC) Advisory Process (DAP)

(Rev. 71, 04-09-04)

The DMERC shall establish a forum of DME advisory workgroups in each region to discuss DME issues and concerns with physicians, clinicians, beneficiaries, suppliers, and manufacturers. Options for this forum should include ad hoc workgroups that are time-limited and/or topic specific. Advisory participants do not advise the Federal Government. Therefore, the rules governing open meetings of Federal Government committees do not apply to the DAP process. Encourage individuals who are concerned with the issues or processes pertaining to DME to attend.

The purpose of the DAP is to provide:

- A formal mechanism to obtain input regarding Regional LCDs (RLCDs) development and revision;
- A mechanism to discuss and improve administrative policies that are within the DMERCs' discretion; and
- A forum for information exchange between the DMERCs, physicians, clinicians, beneficiaries, suppliers, and manufacturers.

13.9 - Provider Education Regarding LCDs

(Rev. 174, Issued: 11-17-06, Effective: 10-01-06, Implementation: 10-06-06)

Contractors shall educate the provider community on new or significantly revised LCDs (e.g., training sessions, speaking at society meetings or writing articles in the society's newsletter). This function shall be charged to provider outreach and education (POE). Inquiries of a clinical

nature, such as the rationale behind coverage of certain items or services, shall be handled within medical review (MR), the department responsible for the development of the LCD.

Carriers are required to publish DMERC summary policies, and other pertinent information supplied by DMERCs, as requested, as part of regular bulletin distributions.

13.10 - Application of LCD
(Rev. 71, 04-09-04)

Contractors should apply LCDs to claims on either a prepayment or postpayment basis. If a contractor decides to enforce an LCD on a prepayment basis, the contractor shall design an MR edit. (See PIM Chapter 3, §3.5) Contractors have flexibility to add, alter, or eliminate MR edits at any time. Contractors should not apply a LCD retroactively to claims processed prior to the effective date of the policy.

13.11 - LCD Reconsideration Process
(Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

Contractors who have the task of developing LCDs shall have an LCD Reconsideration Process in accordance with the following instructions.

A. Purpose

The LCD Reconsideration Process is a mechanism by which interested parties can request a revision to an LCD.

B. Scope

The LCD Reconsideration Process is available only for final LCDs. The whole LCD or any provision of the LCD may be reconsidered.

C. General

Contractors shall respond timely to requests for LCD reconsideration. In addition, contractors have the discretion to revise or retire their LCDs at any time on their own initiatives.

D. Web site Requirements for the LCD Reconsideration Process

Contractors shall add to their current Web sites information on the LCD Reconsideration Process. This information should be on the home page or linked to another location. It shall be labeled "LCD Reconsideration Process" and shall include:

- A description of the LCD Reconsideration Process; and
- Instructions for submitting LCD reconsideration requests, including postal, e-mail, and fax addresses where requests may be submitted.

E. Valid LCD Reconsideration Request Requirements